

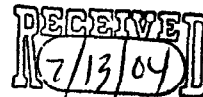
W H O L E W O R L D B O T A N I C A L S[®]

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VIA UPS NEXT DAY AIR

July 9, 2004

Dr. Robert Moore
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740



Re: Fulfillment of Reporting Obligation Under 21 U.S.C. § 343 (r) and 21 C.F.R. § 101.93

Dear Dr. Moore:

Whole World Botanicals, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Whole World Botanicals retains scientific documentation supporting the statements.

1. Supplement Brand Name

Royal Break-Stone

Ingredients

Phyllanthus Niruri (whole leaf, root and stem extract), gelatin, purified water.

Text of Statements of Nutritional Support

Promotes healthy kidney, bladder and gallbladder function.

Recent scientific research has demonstrated that phyllanthin, hypophyllanthin, triacontanol and tricontanol extracted from Phyllanthus niruri have all demonstrated antihepatotoxic properties. The presence of at least one antispasmodic alkaloid is believed to be responsible for the smooth muscle relaxation in the biliary and urinary tract.

Called "Chanca Piedra" in South America, it has been found to promote easy bile flow from the gallbladder to the liver and support free urine flow into the bladder.

A powerful and safe kidney, gallbladder and liver support.

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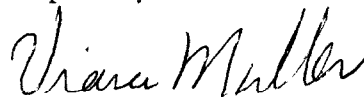
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In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93 (c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."**

Respectfully submitted,

A handwritten signature in cursive script, reading "Viana Muller".

Viana Muller, PhD.
President